

al. disclose intervertebral implants made of metal or a rigid synthetic material (see specification, column 2, line 38), having "ribs" 13, 14 and 16 which function in this implant to "...prevent both axial movement in translation and rotation of the implant, the teeth becoming embedded in the vertebrae" (Godefroy et al., column 2, lines 57-61). In contrast, the tabs of applicants' intervertebral implant are retained within a preformed recess within the vertebra, permitting access to soft or cancellous bone.

Thus, nothing in Godefroy et al. would lead one skilled in the art to applicants' intervertebral implant, which is made of bone or material derived from bone and has at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within the vertebral body. As one skilled in the art would recognize, there are significant differences between using metal or rigid synthetic materials as implants compared with natural bone or material derived from bone. In addition, there are significant differences between having tabs or fins which cut into the vertebral plate, as in Godefroy et al., and having a preformed recess in the vertebrae which retains the tabs of an implant and permits access to cancellous or soft bone which occurs with applicants' invention.

Specifically, these differences include, but are not limited to, the following:

1. bone from the vertebrae adjacent to an intervertebral implant will grow onto the surface of a bone or bone-derived implant, something that will not occur with a metal or synthetic material;

2. a bone or bone-derived implant will eventually be replaced by the natural bone tissue from the recipient of the implant and there will be thus less stress-shielding compared with a metal or synthetic implant. Stress shielding refers to the fact that a metal implant will carry stress rather than the adjacent

bone, thus the bone in contact with the metal implant will not be as strong in carrying loads or when placed under stress;

3. should the implant need to be removed for any reason, a bone or bone-derived implant will be easier to remove, with less removal of additional vertebral tissue, as the removal of a metal implant will require the removal of additional healthy vertebral tissue;

4. the placement of the tabs into the preformed recess in the vertebrae permit a much more predictable placement of the implant than the cutting fins of Godefroy et al., which will wedge into the vertebral plate. Moreover, during the process of forming the preformed recess, weak spots in the vertebrae may be identified, and the resulting implant will be much better suited for bearing weight;

5. the preformed recess permits access of the implant to cancellous or "soft" bone tissue, where the majority of regenerative bone cells are located, thus permitting enhanced fusion of the implant with the adjacent vertebrae.

For the foregoing reasons, applicants submit that the invention of the amended claims is not anticipated by, and is nonobvious over, Godefroy et al.

The Examiner has rejected Claims 1, 2, 4, 5, 8, 9, 21 and 24 under 35 U.S.C. §102(e) as anticipated by Marino U.S. Patent No. 6,290,724 ("Marino").

As with the rejection based on Godefroy et al., the Examiner has declined to give the "bone or bone-derived" limitation of the previously pending claims any patentable weight due to this limitation being recited in the preamble, as distinguished from the body, of the rejected claims. The Examiner also considers the modifier "substantially" in the claim expression "substantially cylindrical body" to be "broad and relatively unlimited".

As indicated above in the discussion of the registration over Godefroy et al., Claim 1 has

been amended so that the limitation "formed from bone or material derived from bone" is now in the body of the claim and recites the features of the tabs (i.e., their configuration and dimensions) which provide for the retention of the tabs in corresponding recesses within a vertebral body.

Nowhere does Marino disclose an intervertebral implant formed from bone or material derived from bone or an intervertebral implant having at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within the vertebral body as presently recited in amended Claim 1. Rather, Marino discloses, as shown in Fig. 7, that when intervertebral insert 23 is installed (by being rotated, or cammed, into place), substantially the entire body of each anchoring fin 36 engages the vertebral endplates.

As noted above with respect to Godefroy et al., applicants' tabs do not cut into the vertebral end plate but, instead, are retained within a recess within the vertebral body where they have access to cancellous bone. Moreover, applicants respectfully submit that the fins of the Marino device must be made of some material besides bone or material derived from bone as they are too thin and would be too fragile to cut into bone were they themselves made of bone. Accordingly, the insert of Marino could not function as intended were its insert, including its fins, made of bone.

Thus, nothing in Marino would lead one skilled in the art to applicants' intervertebral implant. As noted above with respect to Godefroy et al., one skilled in the art would recognize the significant differences between having tabs or fins which cut into the vertebral plate and applicants' preformed recess in the vertebrae which will permit access to cancellous bone. These differences include the fact that the tabs of applicants' implant permit a much more predictable placement of the implant in the preformed recess in the vertebra than the cutting fins of Marino,

which will wedge into the vertebral plates. Moreover, the use of a preformed recess as set forth in applicants' claims will permit access of the implant to cancellous bone tissue where the majority of regenerative bone cells are located, thus facilitating the desired fusion of the implant with the adjacent vertebrae.

As for the Examiner's objection to the use of the expression "substantially", this term and other claim terms such as "about", "essentially", "approximately", and the like, while imprecise, have nevertheless long been accepted by the United States Patent and Trademark Office and the courts as sufficiently definite so as to comply with the statutory requirement for definiteness of 35 U.S.C. § 112, second paragraph. *See, e.g., Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 821-22, 6 USPQ2d 2010, 2012 (Fed. Cir. 1988).

In view of the foregoing, applicants believe that the invention of their amended claims is not anticipated by, and is nonobvious over, Marino.

The examiner has rejected Claim 20 as obvious under 35 U.S.C. §103(a) over Marino in view of U.S. Patent No. 5,676,146 ("Scarborough"). The examiner applies these disclosures using the same language contained in the prior Office Action, dated April 19, 2002, as follows:

...Marino is explained supra. However, Marino does not disclose the use of animal bone for the implant. Scarborough teaches to use animal bone for an implant, col. 2, lines 13-15 and for vertebral repair, col. 3, lines 11-22. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Scarborough in the implant of Marino in order to provide a radiolucent material for easier tracking the implant after implantation.

Dependent Claim 20 incorporates therein all the limitations of its base independent claims. As noted above with respect to the 35 U.S.C. §102(e) rejection, Marino nowhere discloses or suggests an intervertebral implant having at least two tabs extending radially

outward from the substantially cylindrical body portion of the implant, said tabs possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses defined within the vertebral body. Rather, Marino discloses that when its intervertebral insert is installed (by being rotated, or cammed, into place), substantially the entire body of each anchoring fin engages the vertebral endplates. As also noted above, one skilled in the art would recognize the significant differences between having tabs or fins which cut into the vertebral plate and applicants' preformed recess in the vertebrae which will permit access to cancellous or soft bone.

Scarborough is directed to surgical implants containing radiopaque markers which permit the determination of the position and/or orientation of the implant following surgical implantation. There simply is no teaching or suggestion in Scarborough that its implant should have tabs which are rotated into preformed recesses within the vertebral body.

Accordingly, neither Marino nor Scarborough, alone or in combination, render Claim 20 obvious under 35 U.S.C. § 103(a). Withdrawal of the rejection of Claim 20 is therefore respectfully requested.

The examiner has rejected Claim 22 as obvious under 35 U.S.C. §103(a) over Marino in view of Lewandrowski et al. Here again the examiner applies these disclosures using the same language contained in the prior Office Action, dated April 19, 2002, as follows:

...Marino is explained supra. However, Marino does not disclose the surface is demineralized. Lewandrowski et al. teach that demineralization enhances bone osteoinductive properties, p.365. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Lewandrowski et al. in the implant of Marino in order to provide a prosthesis capable of stabilizing the vertebrae while stimulate bone ingrowth.

Dependent Claim 22 incorporates all the limitations of the base independent claims. As

noted above, nowhere does Marino disclose or suggest an intervertebral implant having at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses defined within the vertebral body. Rather, Marino discloses that when its intervertebral insert is installed (by being rotated, or cammed, into place), substantially the entire body of each anchoring fin engages the vertebral endplates. As also noted above, one skilled in the art would recognize the significant differences between having tabs or fins which cut into the vertebral plate and applicants' preformed recess in the vertebrae which will permit access to cancellous or soft bone.

Lewandrowski et al. fails to remedy the deficiencies of Marino. Lewandrowski et al. is directed to the kinetics of cortical bone demineralization. There simply is no teaching or suggestion in Lewandrowski et al. that such demineralized bone could be utilized with a vertebral implant having tabs which are rotated into preformed recess formed within the vertebral body.

Accordingly, neither Marino nor Lewandrowski et al., alone or in combination, render Claim 22 obvious. Withdrawal of the rejection of Claim 22 is therefore respectfully requested.

The examiner has rejected Claim 23 as obvious under 35 U.S.C. §103(a) over Marino in view of U.S. Patent No. 5,445,639 ("Kuslich et al."). Again, the examiner applies these disclosures using the same language contained in the prior Office Action, dated April 19, 2002, as follows:

...Marino is explained supra. Marino discloses forming a core and the implant is positioned by rotating, col. 14, lines 12-26. Marino also discloses implants and the vertebral space that the implant engages are often matched with respect to one another, col. 4, lines 10-24. However, Marino does not disclose the step of forming a stepped bore in a portion of the vertebrae. Kuslich et al. teach to bore areas for vertebral implants with progressively increased blades that can be interpreted to be a stepped bore form, col. 7,

lines 55-66. Fig. 17 shows an enlarged chamber or stepped bore. Kuslich also teaches the stepped bore can be used for dowels or tabs. It would have been obvious to one of ordinary skill in the art to use the method of boring vertebrae in a stepped fashion as taught by Kuslich et al. for inserting the implant of Marino in the implanting procedure in order to provide a ready-made chamber that would not require any forceful rotation or positioning.

As noted above, nowhere does Marino disclose or suggest an intervertebral implant having at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses defined within the vertebral body. In addition, the Examiner admits in the Office Action that "Marino does not disclose the step of forming a stepped bore in a portion of the vertebrae" (see page 4 of the Office Action).

Kuslich et al. fails to remedy the deficiencies of Marino. Kuslich et al. is directed to a surgical tool capable of cutting into contiguous vertebrae to form a chamber. Contrary to the Examiner's assertion, Kuslich et al. does not refer to tabs. While Kuslich et al. teaches that such a chamber can receive a dowel for dowel-type interbody fusion, there simply is no teaching or suggestion in Kuslich et al. of applicants' intervertebral implant, which has tabs which are rotated into preformed recesses formed within the vertebral body.

Accordingly, neither Marino nor Kuslich et al., alone or in combination, render Claim 23 obvious. Withdrawal of the rejection of Claim 23 is therefore respectfully requested.

Favorable action on the merits of Claims 1, 2, 4-9 and 20-24 as presented herein is respectfully requested.

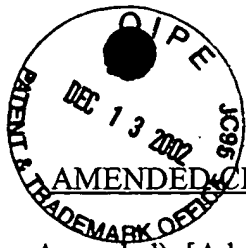
Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Peter G. Dilworth".

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AMENDED CLAIMS MARKED TO SHOW CHANGES

1. (Twice Amended). [A bone or bone-derived] An intervertebral implant comprising a substantially cylindrical body portion having a first end and a second end[;] and

at least two tabs extending radially outward from the substantially cylindrical body portion, each of the at least two tabs [being longitudinally displaced from the first and second ends, each of said tabs being configured for retention within a preformed recess within] possessing a configuration and dimensions complementing the configuration and dimensions of corresponding preformed recesses within a vertebral body, the body portion and tabs being formed from bone or material derived from bone.

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